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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,607	03/26/2001	Fei Yang	DEX-0201	7851

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EXAMINER

HARRIS, ALANA M

ART UNIT PAPER NUMBER

1642

DATE MAILED: 08/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/817,607	<b>Applicant(s)</b> FEI YANG	
	<b>Examiner</b> Alana M. Harris, Ph.D.	<b>Art Unit</b> 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on 21 July 2003.

2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 1, 3-6 and 9 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1, 3-6 and 9 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All   b) ☐ Some \*   c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

***Response to Arguments and Amendments***

1. Claims 1, 3-6 and 9 are pending.

Claim 1 has been amended.

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Claims 1, 3-6 and 9 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Information Disclosure Statement***

3. The Examiner notified Applicants in Paper numbers 9 and 12 (mailed August 13, 2003 and March 20, 2003, respectively) that the information disclosure statement filed September 24, 2001 as Paper No. 5 contained documents that did not accompany the instant application for review. In response Applicants assert that these "[r]eferences AB, AN and AP are not material to the patentability of the instant invention and need not be considered by the Examiner in this prosecution."

***Withdrawn Rejections***

***Claim Rejections - 35 USC § 112***

4. The rejection of claims 1, 3-6 and 9 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time

the application was filed, had possession of the claimed invention is withdrawn in light of the amendment to claim 1.

5. The rejection of claims 1, 3-6 and 9 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn in light of the amendment to claim 1.

6. The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicants' amendment to the claim.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

7. Claims 1, 3-6 and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth SEQ ID NO: 8, a colon specific gene (CSG) and not a nucleic acid sequence having at least 95% identity with SEQ ID NO: 8 contained

with a vector and host cell and a method for producing the encoded polypeptide, which is to be implemented in Applicants' methods.

*Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Applicants are not required to disclose every species encompassed by a genus. For example as indicated in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Applicants broadly claim polynucleotides comprising a nucleic acid sequence having at least 95% identity with SEQ ID NO: 8. These variants of SEQ ID NO: 8 are not of record in the disclosure. Applicant is not entitled, nor is the specification enabled for the use of this infinite number of polynucleotides which may share 95% sequence

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homology with SEQ ID NO: 8, but may or may not be effective as a breast cancer marker. Applicant is not permitted to claim all polynucleotides that are encompassed by the claims, hence not entitled to the wide breadth of the claims at issue. There is no disclosure of mutants or variants of SEQ ID NO: 8 in the specification. There is no description of which nucleic acid residues of SEQ ID NO: 8 should be retained or compromised in order to yield a nucleic acid with at least 95% identity or information regarding the encoded protein's structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure.

This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

8. Claims 1, 3-6 and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' claims encompass an isolated polynucleotide (SEQ ID NO: 8), as well as a nucleic acid sequence having at least 95% identity with SEQ ID NO: 8. A nucleic acid with limited sequence homology will more than likely not encode the same protein encoded by SEQ ID NO: 8 (also known as Clone Id clnc00000827). The said claims also include a nucleic acid sequence having at least 95% identity with SEQ ID NO: 8

contained within a vector and host cell, a method for producing said polynucleotide,  
regarded as a CSG molecule and using the said molecule for diagnoses of colon  
cancer.

The Examiner set forth in Paper number 12, mailed March 20, 2003 that Applicants' specification, as well as the declaration submitted on January 13, 2003 evidence the diagnostic applicability of SEQ ID NO: 8. However, neither the specification nor declaration provide support for the use of polynucleotides with at least 95% identity of SEQ ID NO: 8. On pages 57 and 58 the application provides Tables 4-6, which show levels of expression of sqcln017 (also known as SEQ ID NO: 8 or Clone Id clnc00000827) in numerous samples including normal samples and colon cancer samples. And Dr. Macina's declaration asserts that the indication of the level of colon tissue specific expression of the sqcln017 is higher compared to all the other tissue types tested. None of these tables exemplify the discriminate detection of colon cancer with polynucleotides other than SEQ ID NO: 8 (sqcln017). The specification does not enable one of ordinary skill in the art to definitively assess the incidence of colon cancer with polynucleotides other than SEQ ID NO: 8. There is insufficient evidence provided to support the use of the undescribed sequences in a diagnostic method for colon cancer. There is no disclosure designating what changes to the coding sequences could be tolerated enabling one of ordinary skill in the art to make and use the said sequences in any diagnostic method. The experimental design presented in the specification lacks information regarding the applicability of polynucleotide sequences other than SEQ ID NO: 8 in diagnostic methods relative to colon cancer. The

specification provides essentially no guidance as to which of the infinite possible choices is likely to be successful. While the Lazar (Molecular and Cellular Biology 8(3): 1247-1252, March 1988) article of record discusses the state of the art in peptide chemistry it substantiates the fact that the introduction of mutations in an amino acid sequence will yield products with different biological activity from the wild type protein. Likewise, changes in nucleic acid sequences could potentially impact protein structure and function.

Applicants have not set forth any supporting evidence that suggests that polynucleotides other than SEQ ID NO: 8 would be a unique tumor or molecular marker for colon cancer.

Based on the analysis set forth it would require undue experimentation for the skilled artisan to practice this invention because there is no support in the specification for the enablement of the broadly claimed invention. Therefore, in view of the insufficient guidance in the specification, extensive experimentation would be required to enable the claims.

### ***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within



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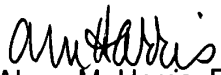
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

**ALANA HARRIS**  
**PATENT EXAMINER**

  
Alana M. Harris, Ph.D.  
July 31, 2003